

## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT RECEIVED

To:

BAXTER HEALTHCARE CORPORATION  
Attn: Reagen, Joseph P.  
One Baxter Parkway  
Deerfield, IL 60015  
UNITED STATES OF AMERICA

RECEIVED

JUL 05 2005

Corporate Patent Administration

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

Corporate Patent Administration

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

29/06/2005

Applicant's or agent's file reference

SMDI-5774B

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2005/038424

International filing date  
(day/month/year)

24/10/2005

Applicant

BAXTER INTERNATIONAL INC.

Filed nationally 7-20-04

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

## Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 48):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

## 4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Peggy Willis

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the International application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/PEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1(bis)(i), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>SMDI - 5774B</b>	<b>FOR FURTHER ACTION</b>		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. <b>PCT/US2005/038424</b>	International filing date (day/month/year) <b>24/10/2005</b>	(Earliest) Priority Date (day/month/year) <b>28/01/2005</b>	
Applicant <b>BAXTER INTERNATIONAL INC.</b>			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☒ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 8  
☒ as suggested by the applicant  
☐ as selected by this Authority, because the applicant failed to suggest a figure  
☐ as selected by this Authority, because this figure better characterizes the invention
- b. ☐ none of the figures is to be published with the abstract

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2005/038424

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid; specifically claims Nos.:
  
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-26

Connector sets of the type wherein a first and a second connector are threaded together, the sets having various technical features providing feedback with regards to substantially completed connection and also preventing disconnection.

---

2. claims: 27-29

Connector set of the type wherein a first and a second connector are threaded together, the set having a disinfectant.

---

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2005/038424

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61M39/10 A61M39/16

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2004/071557 A (BAXTER INTERNATIONAL INC; BAXTER HEALTHCARE S.A; CASTELLANOS, RAFAEL,) 26 August 2004 (2004-08-26) the whole document	1-26
Y	US 2004/238776 A1 (PETERS JOSEPH ET AL) 2 December 2004 (2004-12-02) abstract paragraphs [0029] - [0031]; figures 1-7	1-13
A	US 5 620 427 A (WERSCHMIDT ET AL) 15 April 1997 (1997-04-15) abstract page 19, line 29 - page 20, line 10; figures 19,20	1
	----- -/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

### \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other step when the documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

9 March 2006

Date of mailing of the international search report

29.03.2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Nielsen, M

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2005/038424

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 580 816 A (CAMPBELL ET AL) 8 April 1986 (1986-04-08) abstract column 4, line 66 - column 5, line 47; figure 1 -----	14-16
A	US 2003/006610 A1 (WERTH ALBERT A) 9 January 2003 (2003-01-09) abstract paragraph [0075]; figure 2 -----	14-16
A	US 2003/184090 A1 (GUALA GIANNI) 2 October 2003 (2003-10-02) abstract paragraphs [0019] - [0037]; figures 1-4 -----	14
A	US 2004/087986 A1 (OTT FRIEDRICH) 6 May 2004 (2004-05-06) abstract paragraphs [0067] - [0070]; figures 1,2 -----	14
A	GB 2 343 723 A (MARGARET PAMELA * RICHARDSON; PHILIP * RICHARDSON) 17 May 2000 (2000-05-17) abstract page 9, line 18 - page 10, line 7; figures 1-3 -----	14
A	US 6 183 465 B1 (MEIER KEVIN C ET AL) 6 February 2001 (2001-02-06) abstract; figures 9,10 -----	14
Y	US 2002/010437 A1 (LOPEZ GEORGE A ET AL) 24 January 2002 (2002-01-24) abstract; figures 5,6 -----	17-20
A	WO 2004/033023 A (VYGON; DALLE, VALERY; GUYMARC'H, PIERRICK; CARREZ, JEAN-LUC) 22 April 2004 (2004-04-22) abstract; figures 5-8,12 -----	17
Y	EP 1 331 020 A (JMS CO., LTD) 30 July 2003 (2003-07-30) abstract paragraph [0026] paragraphs [0036] - [0047]; figures 8A-9E -----	21-23
Y	WO 94/23775 A (ABBOTT LABORATORIES) 27 October 1994 (1994-10-27) abstract page 11, last paragraph - page 13, paragraph 1; figures 8,9 -----	24-26

-/--



## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2005/038424

## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 393 101 A (MATKOVICH ET AL) 28 February 1995 (1995-02-28) abstract; figure 1 -----	24
A	EP 1 243 280 A (NIPRO CORPORATION) 25 September 2002 (2002-09-25) abstract; figure 1 -----	24

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2005/038424

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004071557	A	26-08-2004	AU 2004211970 A1 BR P10407366 A EP 1592470 A1 MX PA05008536 A	26-08-2004 10-01-2006 09-11-2005 20-10-2005
US 2004238776	A1	02-12-2004	EP 1432468 A2 GB 2379253 A WO 03020361 A2 GB 2410305 A JP 2005501616 T	30-06-2004 05-03-2003 13-03-2003 27-07-2005 20-01-2005
US 5620427	A	15-04-1997	CA 2219211 A1 DE 69630462 D1 DE 69630462 T2 EP 0869826 A1 WO 9633762 A1 US 6152913 A	31-10-1996 27-11-2003 13-05-2004 14-10-1998 31-10-1996 28-11-2000
US 4580816	A	08-04-1986	NONE	
US 2003006610	A1	09-01-2003	CA 2464348 A1 EP 1470358 A2 WO 03006833 A2 US 2005012332 A1	23-01-2003 27-10-2004 23-01-2003 20-01-2005
US 2003184090	A1	02-10-2003	DE 10310469 A1 IT T020020276 A1	23-10-2003 29-09-2003
US 2004087986	A1	06-05-2004	AU 2003226817 A1 CA 2491148 A1 CN 1662766 A WO 2004001272 A1 EP 1516142 A1 JP 2005536243 T	06-01-2004 31-12-2003 31-08-2005 31-12-2003 23-03-2005 02-12-2005
GB 2343723	A	17-05-2000	NONE	
US 6183465	B1	06-02-2001	AU 774554 B2 AU 7100000 A BR 0015045 A CA 2383525 A1 EP 1207935 A1 JP 2003528651 T MX PA02002205 A WO 0115769 A1	01-07-2004 26-03-2001 02-07-2002 08-03-2001 29-05-2002 30-09-2003 10-04-2003 08-03-2001
US 2002010437	A1	24-01-2002	NONE	
WO 2004033023	A	22-04-2004	AU 2003283505 A1 CA 2489175 A1 EP 1513583 A1 FR 2845607 A1 JP 2006501915 T US 2005225082 A1	04-05-2004 22-04-2004 16-03-2005 16-04-2004 19-01-2006 13-10-2005
EP 1331020	A	30-07-2003	DE 60301676 D1 DE 60301676 T2 HK 1057498 A1	03-11-2005 16-03-2006 03-03-2006

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2005/038424

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 1331020	A		JP	2003210574 A	29-07-2003
			US	2003144647 A1	31-07-2003
-----					
WO 9423775	A	27-10-1994	US	5507733 A	16-04-1996
			US	5437650 A	01-08-1995
-----					
US 5393101	A	28-02-1995	AT	181146 T	15-06-1999
			AT	191267 T	15-04-2000
			AT	210792 T	15-12-2001
			AT	205291 T	15-09-2001
			AT	191548 T	15-04-2000
			AT	256264 T	15-12-2003
			AU	688740 B2	19-03-1998
			AU	5351794 A	26-04-1994
			CA	2101826 A1	03-04-1994
			DE	69325286 D1	15-07-1999
			DE	69325286 T2	09-12-1999
			DE	69328265 D1	04-05-2000
			DE	69328265 T2	02-11-2000
			DE	69328315 D1	11-05-2000
			DE	69328315 T2	09-11-2000
			DE	69330723 D1	11-10-2001
			DE	69330723 T2	11-07-2002
			DE	69331342 D1	24-01-2002
			DE	69331342 T2	23-05-2002
			DE	69333356 D1	22-01-2004
			DE	69333356 T2	07-10-2004
			EP	0668976 A1	30-08-1995
			FR	2696526 A1	08-04-1994
			GB	2286030 A	02-08-1995
			IT	1260691 B	22-04-1996
			JP	3490713 B2	26-01-2004
			JP	8502339 T	12-03-1996
			JP	2003214582 A	30-07-2003
			JP	2003176892 A	27-06-2003
			WO	9408173 A1	14-04-1994
			US	5810398 A	22-09-1998
-----					
EP 1243280	A	25-09-2002	US	2002138039 A1	26-09-2002
			US	2005228348 A1	13-10-2005
-----					